

No human subject research activity will take place until the Human Subject Research ReOpen Guidelines are approved by the President and only those ReOpen Plans approved by the IRB Working Group and VPR will be allowed to proceed. The PI must provide documentation that their ReOpen Plan has been approved by the IRB Working Group and VPR before any scheduling will take place.

STANDARD OPERATING PROCEDURES ADDENDUM FOR COVID -19

The purpose of this SOP addendum is to outline operating procedures for the safe operation of the MNC facility during the COVID-19 pandemic. UMD remains at Phase 1 (limited presence) while readying the campus for research activities. Once specific guidelines for human subjects research have been further defined by the University, the MNC will update its policies and procedures. Human subjects research can be undertaken at the MNC with minimal risk of COVID-19 transmission if the procedures outlined in this document are rigorously followed. Redundant mechanisms are in place to ensure adequate disinfection protocols are performed. These procedures rely on the support of MNC users to share in the burden of these additional protocols. In order to decrease the chance of transmission, the MNC will limit the number of people in the facility at any one time. Therefore, the MNC requires that only one research group at a time be permitted inside. Due to the COVID-19 pandemic, users will also need to complete additional training prior to resumption of their privileges at the MNC.

Overview of Maryland Neuroimaging Center (MNC)



Figure 1: MNC layout while operating in COVID-suppression mode.
The numbered areas refer to the following locations within the MNC:

- Area 1: Outside front entrance. A table will be present with a plexiglass divider. A face shield may be provided to the participant, *if available*. Hand sanitizer may be available in front entryway between doors.
- Area 2: Reception area and desk phone.
- Area 3: Zone 1 bathrooms.
- Area 4: EEG suite. Hand sanitizer, sink, and hand-washing soap available.
- Area 5: Mock suite.
 - 5A: Reception
 - 5B: Locker/changing room
 - 5C: Mock scanner room
 - 5D: Interview/testing room
 - 5E: Waiting room
 - 5F: Storage Closet
- Area 6: Lab workspace.
- Area 7: Zone 2 bathroom. Sink, and hand-washing soap available.
- Area 8: Control room.
- Area 9: Scanner room.

- Area 10: Library.

Overview of Daily Workflow

- The MNC will operate in a restricted access fashion in order to limit the amount of space that will need frequent cleaning, as well as to reduce the number of participants using the facility at any one time. Lab and participant access will be restricted to the main entrance. Note: a limited number of staff will have card key access to the building.
- All staff and lab members will log the date and time of entry and exit for contact tracing.
- All persons will be required to wash hands immediately upon entering MNC, without exception. Everyone entering the MNC must wear a mask at all times.
- Each morning UMD facilities personnel will clean the MNC, paying special attention to disinfecting commonly touched surfaces.
- Each morning, in addition to the standard boot-up procedure, MNC operators will clean and disinfect the commonly touched surfaces in the control, scanner, and equipment rooms.
- Social Distancing: Lab members and MNC staff will practice social distancing, maintaining 6 feet of separation between each other and research participants whenever possible.
- After all scans have been completed for the day, the operator will perform the usual shut-down procedure, taking care to wipe down touched surfaces in the control, scanner, and equipment rooms
- As a general rule: *You touch it, you clean it*. Lab members who do not follow the procedures outlined will not be allowed to utilize the MNC.
- Ensuring the health and safety of all campus community members is everyone's responsibility. Please follow all University and MNC safety guidelines. If you see someone not wearing a mask, kindly remind the individual to follow the mask wearing guideline or to wear their mask properly.

Entry and Screening

1. MNC Staff: Self-monitoring (from UMD's employee guide):
 - a. Each morning they are reporting to work on campus, all employees working on campus must use a self-screening process to assess their risk and record the status of their self-screening. Employees will use an [online symptom monitoring tool](#) and some employees will use a paper form.
 - b. After self-screening, employees exhibiting any concerning symptoms (see below) should not report to campus; they should stay or go home and contact their primary healthcare provider. If they do not have a healthcare provider, they may contact the University Health Center nurse line at (301) 405-HEAL [4325]. They should then follow any instructions given by the healthcare provider before

returning to work. The symptoms listed on this survey may be updated by the University.

c. Concerning Symptoms:

1. Temperature of 100.4 degrees or higher.
2. Any of the following:
 - Chills
 - New onset cough
 - Trouble breathing
 - Sore throat
 - Unusual sinus pain
 - New loss of taste or smell
 - Nausea or vomiting
 - Muscle or body aches
 - Excessive fatigue
 - Diarrhea

d. Employees without access to the online system will use a paper form to track and report their daily symptom details. The employee's supervisor will provide a form with the symptoms of COVID-19 as a reminder, and the employee will verbally confirm upon reporting for work:

1. That they checked for symptoms prior to coming to campus;
2. Whether they have any concerning symptoms.

The supervisor will then record the employee's name and date in an attestation log that does not include any medical information . If the employee is free of concerning symptoms, they will be able to begin work for the day.

Employees who have not completed the symptom monitoring requirement at home will be asked to:

1. Take their own temperature immediately with a thermometer provided by the university;
2. Report any symptoms listed on a laminated form before they begin work.

The laminated form and thermometer will be cleaned and sanitized between each use.

e. Employees who refuse to complete the symptom monitoring requirement at home or on campus will not be allowed to work and/or will be sent home.

f. If the employee has concerning symptoms, they must:

1. Notify their supervisor.
 2. Stay home.
 3. Contact their personal healthcare provider for guidance.
 - If the employee does not have a personal healthcare provider, they should contact the University Health Center for guidance.
 - g. Upon consultation, the healthcare provider will determine whether the employee will be referred for COVID-19 testing. If an employee tests positive for COVID-19, they must notify the University Health Center at healthconcerns@umd.edu.
2. Lab members will ring the doorbell and await MNC staff in Area 1 (outside entrance). Screening of lab members will be conducted there, weather permitting.
 3. On the day of their scan, MNC staff will determine that lab members meet UMD's and the MNC's requirements for employees coming to work upon arriving at the MNC at the outside entrance. This will be accomplished through the following:
 - a. Administration of the COVID-19 screening questionnaire to confirm lab members are not exhibiting or reporting any symptoms.
 - b. Testing with a contactless thermometer to confirm lab members' temperatures are not 100.4 degrees or higher.
 - c. If any of the aforementioned conditions are not met, the lab member(s) will be asked to leave the MNC, and seek medical attention.
 4. Lab members must wear a mask at all times.
 5. For each scan, lab members must arrive *at least* 1 hour before entering the control room. Thirty minutes of this time will be used for cleaning, and the remaining time for participant screening, and any consenting, testing, etc. that must be completed at the MNC. Lab members must wash their hands in Area 3.
 6. Lab members will then proceed to each of the areas they will use for their participant and follow the cleaning procedures outlined in the sections below for each station.
 7. Participants will wait in cars or on the bench outside until lab members are ready to admit them. Lab members will use the phone in Area 2 to call the participant. Participants must wear a mask at all times.
 8. Participants will be screened by MNC staff. Screening will be conducted at the outside entrance of the building, weather permitting. This will be accomplished through the following:
 - a. Administration of the COVID-19 screening questionnaire to confirm the participant is not exhibiting or reporting any symptoms or part of a high-risk group.

- b. Testing with a contactless thermometer to confirm participant's temperature is not 100.4 degrees F or higher.
 - c. If any of the aforementioned conditions are not met, the participant will not be scanned and will be asked to leave the MNC and seek medical attention. The scan will be canceled.
 - d. MRI safety screening will be completed by the operator/Level 2 MNC staff at this time.
9. A single additional visitor, such as a parent or guardian, will be allowed only if necessary to accompany a minor or participant. In order to minimize risk, no other visitors/family members will be permitted in the building. Visitors will be subject to the same screening protocol as the participant and must wear a mask at all times.
10. Assuming no contraindication, the participant (and visitor, if applicable) will be instructed to wash their hands in Area 3.

Note: Cell phones and other electronics can only be brought into the MNC if those entering are arriving by means other than their own car. Lab members and participants must disinfect their phones and other belongings upon entering the MNC and **store them in lockers for the duration of their time at the MNC**, as outlined below. Otherwise, the belongings should be left in the car.

Food deliveries will not be allowed.

Meetings will be conducted virtually whenever possible.

Pre-Scan Procedure

1. Participants will be escorted by lab members to Area 5B, where they will place their clothing (if changing into scrubs), shoes, cell phone, and other belongings into a locker. *Disposable gowns to wear over clothing **may** be provided, if available. A disposable bag **may** be provided for their clothes and belongings, if available.* If a lab member brought their cell phone or other electronics, they **must** be placed in the lab's locker.
2. Lab members will instruct the participant to frequently clean their hands when moving from one area to another. Hand sanitizer will be available in Area 5A. The sink in Area 7 will always be available for hand washing.
3. Any pre-scan testing **that cannot be done remotely** will then be conducted in Area 5C if the mock scanner or mock computer are needed. If they are not needed, 5A or 5D should be utilized, since there is a plexiglass divider on the desks. Lab members and participants will maintain social distancing of at least 6 feet, whenever possible.
4. If a parent/guardian has accompanied the participant, they will wait in Area 10 with a lab member during the scan, on either side of the plexiglass dividers.

5. Before entering Area 8, lab members and participants must wash their hands in Area 7. Lab members should only bring materials into Area 8 that are absolutely necessary for running the scan. No food or drink. No backpacks, purses, laptops, tablets, or cell phones.

Scan Procedure

1. Operator will be wearing a face shield, mask and gloves during interaction with the participant. *The participant may be given a face shield to wear during the scan, if available.* The operator will perform screening of the participant with the metal detector wand. Once cleared, the operator will escort the participant into Area 9 and begin set-up.
2. Operator will only attach equipment to the participant that is strictly necessary to the study using care to avoid as much direct contact as possible. Participants will be asked to insert their own earplugs with instruction from the operator and to hold pads on the sides of their head while being positioned in the head coil.
3. Participant will place the mask worn to the MNC in a disposable bag provided by the MNC. They will be asked to wear a surgical mask (*provided by MNC*) for the duration of the scan.
4. During scanning, the operator and lab member will maintain social distancing of 6 feet whenever possible. Conversation will be kept to a minimum.

Post-Scan Procedure

1. Once the scan ends, the operator will enter Area 9 to remove the participant from the scanner. Once all equipment is taken off of the participant, and they don their mask, they will be escorted into Area 7 to wash their hands. Lab members will also wash hands.
2. The lab member will instruct the participant to return to Area 5B to change back into their clothes, if applicable. Used gloves, disposable gowns/scrubs, and other trash can be disposed of in the normal trash container. Used linens and non-disposable scrubs must be placed in the hamper in the changing room.
3. The operator may remove the face shield if they will not be in contact with anyone for a period of 10 minutes or longer.
4. Lab members will complete any post-testing that cannot be done remotely, then escort the participant out of the facility.
5. After the participant leaves the MNC, lab members will clean all surfaces, door handles, lockers, computers, and other items touched by the lab or the participant.

6. Disposable items, such as gloves or paper from the bed, will be thrown away in a covered trash can that can be opened with a pedal.
7. Operator will post a “Restricted Access” sign on the door of Area 8 from the time the lab members and participants leave until both Areas 8 and 9 are cleaned and allowed to air dry.
8. After the participant and lab members exit the control room, the operator will wait a minimum of 45 minutes to allow the majority of particulates in the air to settle. Participant face shields will be disinfected.
9. Once 45 minutes has elapsed, the operator will wear disposable gloves and must spend an additional 30 minutes cleaning Areas 8 and 9.
 - a. *This includes: MR scanner table with Siemens-approved cleaning wand and wipes; head coil; computer monitor frames, keyboards, and mouses; desk areas; door handles; light switches; MRA console; BioPac tower; amplifier; microphone; intercom; metal-detecting wand; and all physiological recording devices or other peripheral items used and their associated surfaces.*
 - b. Operator will clean and disinfect the button box if used.
10. Once Areas 8 and 9 have been cleaned and air-dried, the “Restricted Access” sign will be removed. Operator will dispose of gloves and wash hands in Area 7.

Cleaning Procedures for Each “Area”

1. Spray and cleaning cloths are the primary method used to disinfect all Areas. *Note: Wet cleaning wipes **may** be provided as well, depending on availability.*
2. Please note the EPA recommends a **2-minute contact time** for the active ingredient to kill SARS-COV-2—this means you need to make sure the surfaces are wet enough not to dry within that period. Please use your best judgment of making sure you refresh your cleaning wipes and/or spray as needed, but also try to use them as efficiently as possible—they are a **precious** resource!
3. Please also note that **ALL** supplies are **ONLY** for the internal use at MNC. Under no circumstances should researchers remove supplies from the MNC for their lab or personal use outside of the MNC.
4. MNC staff will follow guidelines/training on using cleaning agents as directed by UMD Facilities.
5. Wear gloves at all times when cleaning.

Area 1: Outside Front Entrance

Use spray and cloths to clean the table, plexiglass, remote thermometer, and pens.

Area 2: Reception area and phone

Use spray and cloths to clean the phone, the ledge on which the phone rests, plexiglass, and any other touched surfaces.

Area 3: Zone 1 bathrooms

Use spray and cloths to clean door handles, toilet flushing handles, metal holding bars, faucets, soap dispensers, paper towel dispensers, and light switches.

Area 4: EEG suite

- 1) Use spray and cloths to clean door handles, combination lock, EEG room tables, EEG equipment, light switches, sink table, faucet, paper towel dispensers, water containers, small table, mirror, and cabinets.
- 2) Use the wand mop with cleaning wipes to wipe down the floor around the participant EEG setup area.
- 3) Use spray and cloths to clean surfaces in the testing rooms that have been used- keyboards, mouse, light switches, tables, chairs, other equipment

Area 5: Mock suite

- 5A) Mock reception desk:

Use spray and cloths to clean all desk surfaces, items on desk, including phone and intercom, plexiglass, and chairs.

- 5B) Locker room
 - a. Place used linens in the hamper or trash, as appropriate.
 - b. Use spray and cloths to clean the table, hamper, lab locker, scrub locker(s), visitor locker(s), light switch, and door handles.
- 5C) Mock scanner room
 - a. Clean all mock scanner pads and positioners (if/when waterproof ones are obtained) **before and after use** with spray and cloths.
 - b. Clean and disinfect button box (if used).
 - c. Use spray and cloths to clean the mock scanner cushioned table and the hard surface areas around the cushion; all sides of the mock scanner; physician scale, including height rod; presentation computer monitor frame; mouse and keyboard; table; chairs; MRA switchboard; all parts of head coil; and earphones (if we obtain waterproof ones, otherwise earphones will not be used).
 - d. Use the wand mop with cleaning wipes (or cloth and spray if suitable) to wipe down the entire bore area.
 - e. Use spray and cloths to clean the light switches and door handles.

- 5D) Interview/testing room

Use spray and cloths to clean the table; all equipment on the table including, but not limited to: plexiglass, the printer and computer; mouse and keyboard; computer monitor frame, table; chairs; light switch; and door handles.

- 5E) Waiting room

- a. Will be off-limits unless otherwise noted.
- b. If open: Furniture will be placed so that people are not face-to-face.
- c. If open: Use spray and cloths to clean the table, plastic chairs, toy chest, toys, computer tower, TV remote, light switch, and door handles.

- 5F) Storage closet

Use spray and cloths to clean anything touched, including, but not limited to the vacuum, hand-held vacuum, cart, cleaning supplies, light switch, and door handles.

Area 6: Lab workspace

Use spray and cloths to clean all tables and chairs, plexiglass, infant scale, rocking chair, participant light, door handles, toys (if available), and light switch.

Area 7: Zone 2 bathroom

Use spray and cloths to clean door handles, toilet flushing handle, metal holding bar, infant changing station (if used), faucet, soap dispenser, paper towel dispenser, and light switch.

Area 8: Control room

1. The operator will wait 45 minutes after the participant and all lab members have left the control room so most airborne particulate matter has settled before beginning the cleaning process.
2. The operator will use spray and cloths to clean the phone; door access intercom; all computer monitor frames, keyboards, and mouses; all desk surfaces; intercom; microphone; MRA interface box; video switch box; equalizer; operator light; BioPac tower; scanner door button and handle; metal-detecting wands; chairs; light switches; pens; and door handles.

Area 9: Scanner room

1. The operator will wait 45 minutes after the participant and all lab members have left the scanner room so most airborne particulate matter has settled before beginning the

cleaning process. Following this 45 minute period, a minimum of 30 minutes must be allocated to conduct said cleaning.

2. Clean the scanner bed **after each subject** with spray and cloths.
3. Clean all pads and positioners (waterproof ones may be purchased) **after use** with spray and cloths.
4. If applicable, look at all waterproof pads and positioners for tears or fraying to replace when needed.
5. Clean and disinfect button box (if used).
6. Clean participant mirror (non-eye-tracking) with spray and cloth.
7. Clean MRI bore inside and out **after each use** with wand mop and cleaning wipes.
8. Clean all equipment **after each use** including, but not limited to: pulse oximeter, respiration belt, shock and EMG cables, earplug containers, earphones, scanner door handle and door open button, tables, and counters with spray and cloths.
9. Clean and disinfect participant's face shield using spray and cloth or other suitable method.

Area 10: Library

Use spray and cloths to wipe table surfaces, chairs, and plexiglass.

Name: _____ Date: _____

COVID-19 Screening Form

Labs must ask the participants 24-48 hours prior to the day of the scan. All personnel, participants, and visitors will be screened by MNC staff before entering the MNC.

Screening Questions

For LAB MEMBERS ONLY: Have you completed the Return to UMD Daily Self-Monitoring for Covid-19 Survey via email or in paper form before coming to campus today? **Yes No**

Are you experiencing any of the following? Do not mark "yes" if a symptom is related to another long-term health condition.

- Temperature of 100.4 degrees F or greater **Temp:** _____
- Chills
- New onset cough
- Trouble breathing
- Sore throat
- Unusual sinus pain
- New loss of taste or smell
- Nausea or vomiting
- Muscle or body aches
- Excessive fatigue
- Diarrhea

Are you awaiting results of a COVID-19 test you had because you had symptoms or were exposed?

- Yes
- No

Are you caring for someone with COVID-19 or possible COVID-19 infection?

- Yes
- No

Have you been in close contact with someone with COVID-19 or possible COVID-19 infection?

- Yes
- No

Have you traveled nationally or internationally to/from an area with widespread or ongoing community spread of COVID-19 within the past 30 days?

(<https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>)

- Yes
- No

If yes, where? _____

Are you part of any of the following groups?

- Over 60 years of age
- Those with underlying health conditions including heart disease, lung disease, or diabetes
- Those with weakened immune systems
- Those who are pregnant or may be pregnant

Lab/Participant/Visitor Signature: _____ MNC: _____